



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/542,509

01/06/2006

David Strand

005092-00075

5918

22910 7590 07/14/2011

BANNER & WITCOFF, LTD.
28 STATE STREET
SUITE 1800
BOSTON, MA 02109-1701

EXAMINER

BALL, JOHN C

ART UNIT

PAPER NUMBER

1759

MAIL DATE

DELIVERY MODE

07/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/542,509 | Applicant(s) STRAND ET AL. | |
| | Examiner J. CHRISTOPHER BALL | Art Unit 1759 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 24 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 24, and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This Office Action is based on the Response filed with the Office on June 27, 2011, regarding the STRAND et al. application.
2. Claims 1-17, 24, and 55 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 is drawn to an electrophoresis device, as it is dependent upon claim 1; however, the claim limitation requires a method step of choosing of an amount of molecular sieve. A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph (*IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, 11-13, 15, 24, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by IVORY et al. (US 6,277,258), submitted to the Office on an information disclosure statement.

Regarding claim 1, Ivory et al. discloses an electrophoresis device for focusing a charged analyte (Abstract; Figures 1 and 4) comprising: a separation chamber (12) having inlet and outlet ports (114 and 116) defining a flow path for sample fluid (Column 8, lines 17-19); electrodes (22) separated from the separation chamber by a membrane (16) and operative to generate an electric field gradient in the separation chamber (Column 5, lines 10-30); and molecular sieve, in the form of a fluid medium including a chromatography support medium or packing (Column 6, lines 30-44) in the separation chamber operative to shift the location at which a stationary focused band of analyte forms (Column 3, lines 28-32) under a given set of focusing parameters including at least the electric field gradient and the hydrodynamic force of sample fluid flow (Column 5, lines 10-30; Column 8, lines 18-21). The molecular sieve taught by Ivory would place

Art Unit: 1759

the stationary focused band of analyte in a location that is different than the location the stationary focused band would be without the molecular sieve under a given set of focusing process parameters.

Regarding claim 2, IVORY teaches a gradient in the electric field. (Column 5, lines 10-16).

Regarding claim 3, IVORY teaches an electrode chamber (14) containing the electrodes (22) and separated from the separation chamber by a permeable membrane (16) (Column 5, lines 39-44).

Regarding claim 5, IVORY teaches an electrode array (Column 8, lines 8-10).

Regarding claim 6, IVORY teaches individual control of the electrodes (Column 6, lines 9-12).

Regarding claim 7, IVORY teaches dynamic control of the electric field gradient generated by the electrode array (Column 6, lines 9-12).

Art Unit: 1759

Regarding claims 11-13 and 15, IVORY teaches the sieve comprising a gel, an organic gel, an inorganic gel, and a soluble gel (Column 6, lines 30-44; Table 4).

Regarding claim 24, IVORY teaches a method for focusing a charged analyte comprising: providing an electrophoresis device as described in claim 1 (Column 19, line 34 - column 21, line 31; and see treatment above), and introducing a flow of sample fluid into the separation chamber, the sample fluid comprising the analyte (Column 21, lines 36-37); energizing at least a subset of the electrodes to establish an electric field gradient in the separation chamber effective to focus the analyte in the separation chamber (Column 21, lines 37-49). The molecular sieve taught by Ivory would place the stationary focused band of analyte in a location that is different than the location the stationary focused band would be without the molecular sieve under a given set of focusing process parameters.

Regarding claim 55, IVORY teaches a molecular sieve, in the form of a fluid medium including a chromatography support medium or packing (Column 6, lines 30-44) in the separation chamber operative to shift the location at which a stationary focused band of analyte forms (Column 3, lines 28-32) under a given set of focusing parameters including at least the electric field gradient and the hydrodynamic force of sample fluid flow (Column 5, lines 10-30; Column 8, lines

Art Unit: 1759

18-21). As IVORY teaches the same materials as disclosed for use as molecular sieves in the instant specification, they will have the exact same characteristics.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of IVORY et al. (US 5,298,143; herein after referred to as "IVORY B"), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claims 1 and 3, as outlined above.

IVORY does not disclose a device wherein the electrode chamber is non-uniform and the separation chamber is encircled longitudinally by the electrode chamber.

However, IVORY B disclose a similar electrophoresis device (Figure 20) in which the electrode chamber (650) is nonuniform (varying cross-section) and encircles the separation chamber (653) longitudinally.

At the time of the present invention, it would have been obvious to one having ordinary skill in the art to modify the device of IVORY by configuring the system cylindrically with a non-uniform electrode chamber, as taught by IVORY B because it gives more membrane surface area for removal of low-molecular weight impurities and a more uniform electric field in the separation chamber.

10. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of IVORY et al. (US 5,298,143; herein after referred to as "IVORY B"), an article by KOEGLER et al. ("Focusing proteins in an electric field gradient", JOURNAL OF CHROMATOGRAPHY A, vol. 726, no. 1-2, March 1996, p. 229-236), and a portion of a book by LI (Capillary

Electrophoresis Principles, Practice, and Applications, New York: Elsevier Science Publications, 1992, pp. 192-200), all submitted to the Office on an information disclosure statement.

IVORY teaches the limitations of claim 1, as outlined above. IVORY additionally teaches the dependence of band position on the electrophoretic mobility of an analyte. (Column 14, lines 16-33).

IVORY does not specifically disclose devices or methods whereby the position shift of the focused band of analyte for a given set of conditions varies by molecular weight, as recited in claim 8, molecular size as recited in claim 9, or is proportional to the molecular weight as recited in claim 10.

However, KOEGLER and IVORY B disclose a theory describing the mechanism of separation in an electric field gradient focusing apparatus such as those disclosed by IVORY, suggesting dependence of mobility on molecular size and density.

Additionally, LI discloses the dependence of electrophoretic mobility of proteins on their molecular mass, and discusses the use of polyacrylamide gel electrophoresis to separate proteins based on mass. (Page 192)

At the time of the present invention, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device and method of IVORY by using a gel that separates analytes on the basis of molecular size or molecular weight, as taught by KOEGLER and IVORY B,

Art Unit: 1759

because it would give a separation with higher resolution. And, given the teachings of LI, the separation of the analytes would be proportional to their molecular weight, among other variables.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of ANDERSON et al. (US 5,993,627), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claims 1 and 11, as outlined above.

IVORY does not explicitly teach the use of a fixed gel.

However, ANDERSON discloses the use of cast slab gels, which are fixed in molds (Column 8, lines 27-31, 50-53).

At the time of the present invention, it would have been obvious to one having ordinary skill in the art to modify the device of IVORY by using a gel fixed within the separation chamber, as taught by ANDERSON, because it would allow collection of purified protein with minimal contamination from the separation matrix.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of MENCHEN et al. (US 5,759,369), both submitted to the Office on an information disclosure statement.

Art Unit: 1759

IVORY teaches all the limitations of claims 1 and 11, as outlined above.

IVORY does not explicitly teach the use of a gel having molecules with molecular weight between 2000 and 100,000 Da.

However, MENCHEN discloses a viscous polymer medium for use in electrophoresis, which contains molecules having molecular weight in the range of 4-500 kDa (Column 9, lines 63-67).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of IVORY by selecting a gel with molecular weight within the range of 4-100 kDa, as taught by MENCHEN, because IVORY suggest the suitability of a broad range of media (including polymer solutions) for use in their device (Column 6, lines 30-44).

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of WILSON et al. (US 5,019,232), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claim 1, as outlined above.

IVORY does not explicitly teach the use of a molecular sieve comprising zeolite.

However, WILSON discloses a medium for electrophoresis comprising polymer fibrils, particulate support, and a modifier such as zeolite (Column 6, lines 1-10).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of IVORY by using a molecular sieve comprising zeolite, as taught by WILSON, because IVORY suggest the suitability of a broad range of media (including porous particulate chromatography packings) for use in the described device (Column 6, lines 30-44).

Response to Arguments

14. Applicant's arguments filed June 27, 2011, have been fully considered but they are not persuasive. Applicant argues all the pending claims are patentable based on the assertion that Ivory et al. (US 6,277,258; hereinafter "IVORY") does not teach a molecular sieve that shifts the location of the stationary focused band of analyte, as required in independent claims 1 and 24 (Remarks, p. 6-11).

However, the instant disclosure defines a molecular sieve and gives examples of materials that are molecular sieve ([0062] of the US Patent Application Publication, 2006/0124459 A1), including gels of various types. IVORY explicitly states as a possible support medium in the fluid medium, among other things, gel filtration supports (Col. 6, lines 43-44). This means one of the general classes of molecular sieve of the instant application includes material disclosed by the prior art reference, IVORY. Additionally, the instant specification in the same paragraph lists specific gels including "linear polyacrylamide, polyvinyl alcohol, methyl cellulose . . ." IVORY explicitly states the fluid medium

Art Unit: 1759

can contain polymer solutions, and gives as examples, "linear polyacrylamide, polyvinyl alcohol, methyl cellulose solutions" (Col. 6, lines 35-36).

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. (*In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)). Therefore, the arguments are not persuasive, and the art rejections are maintained.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

Art Unit: 1759

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Barton can be reached on (571) 272-1307. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1759

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCB
07/13/2011

/Jeffrey T Barton/
Supervisory Patent Examiner, Art Unit 1759
13 July 2011